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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,480	11/08/2001	Craig A. Rosen	PS500P1	5616

22195 7590 03/10/2004

HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
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EXAMINER	
SHEINBERG, MONIKA B	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/986,480	ROSEN ET AL.	
	Examiner	Art Unit	
	Monika B Sheinberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-36 and 47-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-36 and 47-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Response to Amendment filed 08 December 2003

1. Applicants' arguments, filed: 08 December 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. The cancellation of claims 1, 8, 13, 15, 17-21, 23 and 37-46 are acknowledged.

3. Claims 25-36 and 47-56 are pending.

Priority

4. The correction of the effective filing date and priority date of May 15, 1999 to May 13, 1999 is acknowledged. The priority date of the instant application is May 13, 1999.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 101/112

5. The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

6. The rejection of claims 25-36 and 47-56 is reiterated and maintained under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well-established utility.

7. The specification provides observational evidence on page 97 of an undefined level of differential gene expression in various non-specific tissues and cells by nucleic acid analysis and not by protein analysis. Page 97 of the specification recites the utility of the protein encoded by Gene No. 55 (SEQ ID NO: 225) is for diagnosis and treatment of testicular cancer and associated metastases due to the gene being "expressed in testes and to a lesser extent in cDNA libraries derived from CD34 positive cells (cord blood), Soares melanocyte 2NbHM, normalized infant brain, fetal kidney, whole brain, and Merkel cells. It is noted that expression of an undisclosed amount in any of the above, was observed in cells not limited to the male reproductive system therefore the expression in testes does not prove useful in diagnostic assays or treatment of testicular cancer. No characterization of the actual potential functional activity of the claimed protein is disclosed. Since there is no physical protein, the instant invention requires further experimentation to be able to have a protein from which further assays may be performed to determine and/or validate the actual function of the predicted peptide. The potential specific utility of the protein determined by observation of an undefined level of gene expression

difference in various non-specific tissues is not deemed to reasonably support any characterization of the bioactivity of the peptide where nucleic acid analysis and not by protein analysis was performed; no actual protein with a defined functionality or biological activity is disclosed thus there is no certainty of a useful isolated product.

> Biological Activities -
> The polynucleotides or polypeptides, or agonists or antagonists of the present invention can be used in assays to test for one or more biological activities. If these polynucleotides and polypeptides do exhibit activity in a particular assay, it is likely that these molecules may be involved in the diseases associated with the biological activity. Thus, the polynucleotides or polypeptides, or agonists or antagonists could be used to treat the associated disease. Polynucleotides, translation products and antibodies corresponding to this gene may be useful for the diagnosis, prognosis, prevention, and/or treatment of diseases and/or disorders associated with the following systems. (p. 367)

The specification asserts that based on tissue distribution, the polypeptide compounds, and/or protein, may be useful in for diagnosis and treatment of testicular cancer and associated diseases. These associated diseases of the male reproductive system are in a laundry list from page 433 (line 31) to page 435 (line 10). The listed diseases and disorders described by the preferred indications of the polypeptide are non-specific, but covering a wide array of diseases and disorders. The laundry list of diseases or disorders that are encompassed within the above specified indications appear to cover an extremely broad range of disorders. Thus no specific use has actually been indicated as the preferred embodiment of SEQ ID NO: 225. In fact, the specification summarizes modern biotechnology generally (in the ability to utilize the claimed sequence for multiple assays of all sorts) but never connects the elected sequence to any particular or specific utility. This wishlist desire for a utility for the claimed sequence falls short of a readily available utility. Ideally, the use of examples in a given specification typically serve to demonstrate at least the critical limitations and/or requirements in order to make/use an invention. However, the examples are generic in nature and not specific to the elected sequence. The exemplary assays described within the specification are general to any disclosed polypeptide and are non-specific uses that are applicable to proteins in general and not particular or specific to the polypeptide being claimed, SEQ ID NO: 225.

8. In addition, the protein is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. The protein is only slightly characterized by results of tissue distribution based upon a general expression analysis. The

research contemplated by applicant(s) to characterize potential protein products, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities such as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the protein compound(s) such that another non-asserted utility would be well established for the compounds.

9. The rejection of claims 25-36 and 47-56 is also reiterated and maintained under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Response to Arguments

10. The applicant's arguments have been fully considered and have not been found persuasive.

The current USPTO utility guidelines state (*emphasis added*):

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes chromosome markers, or forensic or diagnostic markers. Therefore the credibility of such an assertion would not be questioned, although such a use might fail the- specific and substantial tests (see below).

"Specific Utility" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. ' 10 1.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility."

D. A method of making a material that itself has no specific, substantial, and credible utility. '

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a specific or substantial utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial asserted utility would be considered to be met.

A "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. 'Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

See also the MPEP at 2107 - 2107.02.

11. On page 6, 1st paragraph: Applicant asserts that any utility unless proven 'false' by the examiner fulfill requirements of the utility under 35 USC 101, of which examiner has not provided sufficient evidence. This argument has been thoroughly reviewed but is not found to be persuasive because while the utilities are credible, they are not specific and not substantial. The asserted utilities do not take advantage of the specific structure, sequence, or properties of the claimed SEQ ID NO: 225, but rather are uses common to all polypeptides. The utility of an invention must satisfy three criteria in order to be valid: the utility must be credible, specific, and substantial. Examiner is not challenging the credibility of the instant invention. The assertion that the utility of the present invention is credible (and examiner does not suggest that such uses

are not credible), does not in any way affect the fact that the utility is also non-specific and not substantial. Thus the argument is found non-persuasive.

12. On page 6, 1st paragraph: Applicants assert that Examiner has not met the burden that is necessary to establish and maintain a rejection for lack of utility und 35 USC 101 because the Examiner failed to (a) show the asserted utility is not specific, substantial, and credible; (b) show support for factual findings relied upon; and (c) showed an evaluation of the closest prior art. This argument has been thoroughly reviewed but is not found to be persuasive because with respect to specific, substantial and credible utility, Examiner has demonstrated the lack of specific utility (section #6 above), and lack of substantial utility (section #7) (as stated above, Examiner is not challenging the credibility of the instant invention). With respect to the display of factual findings relied upon, Examiner points to specific sections of the specification as seen in section #6 (i.e. pp. 97, 367, and 433). With respect to the evaluation of the closest prior art, no prior art set forth any well established utility thus it is unclear what prior art Examiner should have cited. With respect to the Reference AA (Genseq ID AAY73899) submitted by Applicants, the prostate specificity of the sequence was disclosed post-filing (2003).

13. On page 6, 3rd paragraph: Applicants assert that the "explanation and reasoning provided by the Examiner is immaterial with regards to utility" with respects to protein isolation "via computational analysis or otherwise" and the potential sequencing errors (lines 1-5). Applicants' arguments have been found persuasive. The statements made in the rejection as directed to computational analysis and potential sequencing errors have been withdrawn from the previous utility rejection. The basis of the statements made in the previous office action was upon the disclosure in the specification that a sequencing error could occur. However there is no evidence of a sequencing error with respect to the amino acid sequence of SEQ ID NO: 225.

14. On page 7: Applicants assert that a specific use for SEQ IDNO: 225 has been identified, "namely as a marker for testicular cancer and for the male reproductive system" (1st paragraph). In addition, applicants submit Reference AA, Genseq ID AAY73899 (2003) for reasons that post-filing date references that provide scientific evidence can be used to 'corroborate' applicants asserted utility. Applicants point to the database entry stating, "that this sequence is a human prostate tumor EST fragment derived protein #86" and that this EST corresponds to SEQ IDNO: 225. Applicants assert that therefore this 3rd party evidence "supports a reasonable correlation

between Protein HCUDW10 and disorders of the male reproductive system" (3rd paragraph). This argument has been thoroughly reviewed but is not found to be persuasive because the specification specifically correlates the secreted protein represented by HCUDW10/SEQ ID NO: 225 to **testicular cancer** and associated metastases: (reiterated from previous action with emphasis added).

> **Page 97 of the specification recites the utility of the protein encoded by Gene No. 55 (SEQ ID NO: 225) is for diagnosis and treatment of testicular cancer and associated metastases due to the gene being "expressed in testes** and to a lesser extent in cDNA libraries derived from CD34 positive cells (cord blood), Soares melanocyte 2NbHM, normalized infant brain, fetal kidney, whole brain, and Merkel cells. It is noted that expression of an undisclosed amount in any of the above, was observed in cells not limited to the male reproductive system therefore the expression in testes does not prove useful in diagnostic assays or treatment of testicular cancer.

In addition, the listed other tissues that demonstrated SEQ ID NO: 225 expression, do not include prostate. Thus the evidence of Reference AA provided, being a sequence of a human prostate tumor EST fragment derived protein, does not provide evidence for SEQ ID NO: 225 being a marker for **testicular cancer**. The specification provides no evidence of the use of SEQ ID NO: 225 as a differential marker for prostate cancer.

15. On the bridging paragraph of pages 7-8; In response to Examiner's 'laundry list' argument, Applicants assert, (emphasis added)

> ... the disclosure of diseases and disorders for the claimed polypeptide does not negate the specificity of any one of [the asserted utilities... It] is common and sensible for an applicant to identify several specific utilities for an invention. ...Nonetheless, Applicants have asserted a specific and substantial utility for the claimed invention – a differential marker for testicular cancer and disorders of the male reproductive system, *i.e.*, **prostate cancer**.

This argument has been thoroughly reviewed but is not found to be persuasive. The specification fails to teach or assert a use for an association between the differential expression of the specific sequence of SEQ ID NO: 225 and prostate cancer. Although prostate cancer may be considered a disease/disorder of the male reproductive system, the specification clearly discloses the nucleic acid encoding SEQ ID NO: 225 to express in the testes and other non-prostate cells/tissues while suggesting SEQ ID NO: 225 as a diagnostic tool for testicular cancer. Although Applicants have disclosed prostate cancer in the specification within a multitude of other potential diseases and disorders on page 392, these listed diseases and disorders are disclosed in reference to all the sequences within the specification on pages 367-445 in a general fashion, while nowhere in the

specification is there a specific teaching or evidence to the differential expression of SEQ ID NO: 225 being diagnostic of prostate cancer.

16. On page 8; Applicants assert that a substantial utility of the claimed polypeptides are as

> reagents for differential identification of the tissue(s) or cell type(s) present in a biological sample and for diagnosis of the disease and conditions which include, but are not limited to, testicular cancer (2nd paragraph).

This argument has been thoroughly reviewed but is not found to be persuasive because as noted in the previous action, the expression of an undisclosed amount of the gene encoding SEQ ID NO: 225 was observed in cell types/tissues not limited to the male reproductive system therefore the expression in testes does not prove useful in diagnostic assays or treatment of testicular cancer (the listed cell types/tissues were from CD34 positive cells (cord blood), Soares melanocyte 2NbHM, normalized infant brain, fetal kidney, whole brain, and Merkel cells). In addition, the testes tissue disclosed also has no indication if it was a normal testes sample or cancerous testes sample or mixed testes sample; thus the expression in the testes is not defined in any fashion. It is not clear from the disclosure in the specification if the nucleic acid encoding SEQ ID NO: 225 is differentially expressed in cancerous testes versus normal testes, or if it is expressed to the same extent in both cancerous and normal testes. Further, no characterization of the actual potential functional activity of the claimed protein is disclosed. The instant invention requires further experimentation to determine and/or validate the actual function of the predicted peptide. The specification only provides results of tissue distribution based upon a general expression analysis. The research contemplated by applicant(s) to characterize potential protein products, does not constitute a specific and substantial utility.

17. Therefore, the arguments are non-persuasive to overcome the rejection.

18. The rejection of claims 25, 26, 28-32 and 34-36 is reiterated and maintained under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

19. WRITTEN DESCRIPTION: Claims 25, 26, 28-32 and 34-36 are directed to a predicted polypeptide sequence.

20. Any variation in amino acid sequence results in a new and independent sequence that does not reliably result in similar or identical biological activities as result for example from altered folding patterns. The claims remain encompassing sequences that are not described by the specification. For example, it would have been known that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. Flanking amino acids are included within the mutations of an amino acid sequence that can alter the folding pattern. For further clarification, sequences encompassed are of any magnitude and/or content that comprise at least the specified region of SEQ ID NO: 225 are included in the above: as seen in claim 25, for example, "an isolated protein *comprising* amino acid residues 31-198 of SEQ ID NO: 225." Absent factual evidence characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no effect. Thus the instant claims are directed to encompass peptide sequences that correspond to sequences from other species, mutated fragment sequences, variants, and so forth. Thus the claim encompass an extremely large genus of peptides, wherein the specification's disclosure of a single sequence of SEQ ID NO: 225 is not representative of this genus. None of these additional sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of a substantially purified peptide molecule comprising the sequence of SEQ ID NO: 225 or a peptide molecule consisting of the specified contiguous fragments of SEQ ID NO: 225, the skilled artisan cannot envision the detailed chemical structure of the

encompassed polypeptides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypetide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997);
>
> *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Accordingly, the specification does not provide a written description of the invention of claims 25, 26, 28-32 and 34-36. This is a rejection based on a lack of WRITTEN DESCRIPTION.

Response to Arguments

21. On page 10-11, bridging paragraph; Applicants assert that "while applicant must 'blaze marks on trees,' rather than 'simply [provided] the public with a forest of tress,' an Applicant is not required to explicitly describe each of the trees in the forest" [in citing *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 USPQ2d 1227 (Fed. Cir. 2000)]. This argument has been thoroughly reviewed but is not found to be persuasive because the specification does not

reflect possession of mutants, variants, or homologs of SEQ IDNO: 225 from any source by merely disclosing the sequence of SEQ ID NO: 225 and general descriptions on how to alter it. For example, isolation of SEQ ID NO: 225 from the deposit HCUDW10 does not reflect possession of mutants or variants of SEQ ID NO: 225, nor possession of peptides of any magnitude and/or content.

22. On page 10, 3rd-4th paragraph; Applicants argue that applicants were in possession of the polypeptides encompassed by the claims because the polynucleotides encoding the claims polypeptides were experimentally isolated and submitted within deposit HCUDW10, while the specification described how to isolate said polypeptide in Example 1. This argument has been thoroughly reviewed but is not found to be persuasive because of reasons stated above in section # 21.

23. Therefore, the arguments are non-persuasive to overcome the rejection.

Conclusion

- The rejection of claims 25-36 and 47-56 is reiterated and maintained under 35 U.S.C. § 101/112 – utility.
- The rejection of claims 25, 26, 28-32 and 34-36 is reiterated and maintained under 35 U.S.C. § 112 – written description.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The central **Fax number is (703) 872-9306.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (571) 272-0749. The examiner can normally be reached on Monday-Friday from 9 A.M to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Jehanne Sitton, can be reached at (571) 272-0752. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (571) 272-0518, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 2, 2004
Monika B. Sheinberg
Art Unit 1634

MBS

Jehanne Sitton
JEHANNE SITTON
PRIMARY EXAMINER
3/2/04